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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,602	09/05/2000	Anders Carlsson	13454NP	4856

7590

09/04/2002

Ralph A Dowell
Dowell & Dowell
Suite 309
1215 Jefferson Davis Highway
Arlington, VA 22202

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/04/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,602

Applicant(s)

CARLSSON ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Amendment C filed July 16, 2002 and Supplementary Amendment D filed on July 29, 2002 are acknowledged. Claims 1-13 are included in the prosecution of this application.

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6068860 in view of WO 95/20943.

Carlsson et al (6068860) teach a pharmaceutical formulation containing a glucocorticoid, foscarnet, and galactolipids (example 5). The galactolipids are from oats (example 5). The galactolipid material further contains digalactosyldiaacylglycerol. The reference teaches the actives dissolved or encapsulated in a liposome containing galactolipids, which penetrates the skin rapidly provides an improved accumulation of foscarnet in the living epidermis, it can sustain a high concentration of the active, and is chemically and physically stable (col. 4, lines 10-25 and col. 10, line 35 to col. 11, lines 60). Further, the instant galactolipid and glycerol is taught (col. 5, lines 12-66).

Carlsson et al do not teach another oily non-polar lipid in the composition or the instant amount of galactolipid.

Carlsson et al (WO) discloses a topical oil-in water emulsion containing galactolipids in the instantly claimed amounts. The galactolipids are from oats (pg. 7). The composition further contains digalactosyldiaacylglycerol (examples and claims). The reference includes glycerol in the composition (examples). Carlsson teaches the use of oils such as MCT and fatty acids such linolenic acid (pg 13) have therapeutic actions in themselves (pg. 5). The reference teaches topical application and since the oil-in-water formulation taught is a liquid, lotion is implicit. Carlsson et al (WO) that "an intrinsic beneficial feature of the galactolipids is the galactose units comprising the polar headgroup in each lipid molecule, which may sterically stabilize the emulsion droplets, and thus provide for a prolonged life-span when injected into the blood stream" on page 5, lines 1-5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of US patent 6068860 and WO 95/20943 since both references disclose topical administration of actives and galactolipids carriers. One would be motivated to use add another lipid in '860 since Carlsson teaches other oils have therapeutic actions too; therefore one of ordinary skill in the art would have a reasonable expectation of an additive if not synergistic effect.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al (6068860) in view of WO 95/20943 in further view of Horrobin (4444755).

Carlsson et al teach a topical composition containing galactolipids as set forth above. Further, Carlsson et al teach the incorporation of dermatological agents. WO teaches the use of dermatological agents and linolenic acids.

The references do not teach 13-hydroxy-linolenic acid specifically.

Horrobin teaches the use of various essential fatty acids for the treatment of skin conditions such as psoriasis (see abstract, col. 1, line 18 through col. 3, line 39; col. 4, lines 25-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Carlsson et al and Horrobin. One would be motivated to do so since the use of the claimed essential fatty acid as they are known for their effectiveness in the treatment of skin conditions such as psoriasis as evident from Horrobin. Alternately, the use of the emulsions of Carlsson et al in the teachings of Horrobin would have been obvious to one of ordinary skill in the art since Carlsson et al teach that galactolipid emulsions are surprisingly stable (note pages 6 and 7).

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

[Handwritten signature]

August 29, 2002

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[Handwritten signature]
JOSE C. DEES
SUPERVISORY PATENT EXAMINER
1616